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10/620,221	07/15/2003	Gary A. Koppel	22064-71990	8706

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EXAMINER	
ROYDS, LESLIE A	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/620,221	KOPPEL, GARY A.	
	Examiner	Art Unit	
	Leslie A. Royds	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 August 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17* is/are pending in the application.

4a) Of the above claim(s) *1,7-10 and 12-17* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2-6 and 11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10Aug10*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-17 are presented for examination.

Applicant's Amendment and Information Disclosure Statement (IDS) filed August 10, 2010 have each been received and entered into the present application. As reflected by the attached, completed copy of form PTO-1449 (one page), the Examiner has considered the cited references.

Claims 1-17 remain pending. Claims 1, 7-10 and 12-17 remain withdrawn from consideration pursuant to 37 C.F.R. 1.142(b). Claims 2-6 and 11 remain under examination.

Applicant's arguments, filed August 10, 2010, have been fully considered. Rejections and/or objections not reiterated from previous Office Actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set of rejections and/or objections presently being applied to the instant application.

Discrepancy Regarding the Status of Instant Claim 4

Applicant states at p.5 of the Remarks filed August 10, 2010 that "the Examiner has mistakenly excluded claim 4 from the list of withdrawn claims" and alleges that the Examiner has erroneously included claim 4 along with the claims under examination. Applicant presents the status of instant claim 4 as "withdrawn" in the accompanying claim listing.

The basis of these statements is unclear because the inclusion of instant claim 4 with the claims presently under examination was not, as Applicant has alleged, an error. Examination was extended to instant claim 4, which is clearly supported by the content and grounds of rejection as set forth in the previous Office Action dated May 21, 2010. Accordingly, Applicant's withdrawal of claim 4 is improper. Claim 4 remains under examination consistent with the grounds of rejection and statement of claims under examination in the previous Office Action dated May 21, 2010.

Claim Rejections - 35 USC § 112, First Paragraph, Written Description Requirement, New Matter

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 2-6 and 11 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement because the claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for the reasons of record set forth at p.2-6 of the previous Office Action dated May 21, 2010, of which said reasons are herein incorporated by reference.

Response to Applicant's Arguments

Applicant traverses the instant rejection, stating that the specification describes the effective amounts of clavulanic acid that achieve the claimed effects both conceptually and numerically and references p.5, 7, 24-25, 30-33, 35, 37, 40, 42 and 44 in support of his position. Applicant further states that he is not required to provide a description of that which is "readily knowable" by persons skilled in the art. Applicant alleges that one of skill in the art would be able to carry out simple clinical trials during the course of practicing the invention and readily determine the effective amounts for treating a specific patient.

Applicant's traversal has been fully and carefully considered, but fails to be persuasive.

Firstly, Applicant is reminded that rejections under the written description requirement of 35 U.S.C. 112, first paragraph, are set forth when the claim scope is not commensurate with what is disclosed and, therefore, what was in possession of the Applicant at the time of the invention, in the accompanying specification. In the present case, while Applicant's reference to the disclosure at p.5, 7,

24-25, 30-33, 35, 37, 40, 42 and 44 is noted, the disclosure of such portions of the specification provides either a solely functional description (without any description of the actual amounts that would be functional to provide such effects) or a numerical range but in the absence of any description or disclosure that these particular numerical amounts are actually *functional to provide the effects that are recited in the instant claims* (i.e., (1) an amount of clavulanic acid salt(s) or active ester form(s) thereof that hydrolyze *in vivo* to clavulanic acid effective to modulate neurogenic carboxypeptidase or transpeptidase activity in the brain, as recited in claim 11, or (2) an amount of clavulanic acid salt(s) or active ester form(s) thereof that hydrolyze *in vivo* to clavulanic acid effective to provide a cognition enhancing concentration of clavulanic acid in the brain, as recited in claim 2). Absent such description by Applicant, the fact remains that one of skill in the art would have no other recourse but to employ such assay methods or pharmacokinetic experiments to identify those dosage amount(s) that would actually be functional to achieve the effect(s) instantly claimed. In fact, Applicant appears to readily admit that such methods of testing would be required to determine the scope of the claimed dosage amounts at p.6-7 of the Remarks filed August 10, 2010. Note, further, that the issue at hand is not simply to determine what "effective amount" would be necessary to treat a particular patient, but rather what specific amounts of clavulanic acid salt(s) or active ester(s) that hydrolyze *in vivo* to clavulanic acid are effective to (1) modulate neurogenic carboxypeptidase or transpeptidase activity in the brain or (2) provide a cognition enhancing concentration of clavulanic acid in the brain. The claimed effective amounts are tied to a very specific function for which Applicant has failed to provide any description of what would constitute even an exemplary amount effective to perform such a function and, therefore, places the burden of hit or miss testing on the skilled artisan to determine where the metes and bounds of such amounts are actually located.

It is this very need to undertake testing to identify other members of the instantly claimed genus that is a clear basis for concluding a lack of written description for the full scope of effective amounts

instantly claimed because, logically, *Applicant cannot be in possession of that which he has yet to identify*. Instead, Applicant has placed the burden upon the skilled artisan to identify, using methods of pharmacokinetic assessment and measurement techniques, what dosage amounts may be used to achieve the therapeutic effect(s) of the instant claims (i.e., amounts of clavulanic acid salt(s) or active ester(s) that hydrolyze *in vivo* to clavulanic acid are effective to (1) modulate neurogenic carboxypeptidase or transpeptidase activity in the brain or (2) provide a cognition enhancing concentration of clavulanic acid in the brain). This clearly fails to meet Applicant's burden of providing a written description of the invention. A need to hunt for amounts effective to function in the manner claimed is a clear lack of written description because a wish or plan for obtaining the invention as claimed does not provide adequate written description of an invention. In other words, though Applicant has clearly demonstrated that he (or the state of the art as a whole) had a *plan* for how to identify other amounts of the instantly claimed agent that may be amenable for use in the present invention by using particular assay or pharmacokinetic measurements, it remains that *at the time of the invention*, Applicant had not yet identified any of such amounts that function to provide the claimed effects and, therefore, did not have written description of the full scope of the genus of effective amounts instantly claimed.

For these reasons *supra*, and those previously set forth at p.2-6 of the Office Action dated May 21, 2010, rejection of claims 2-6 and 11 is proper.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 2-6 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tew et al. (WO 97/10247; 1997) in view of Cole et al. (U.S. Patent No. 4,110,165; 1978), cited to show a fact, and in view of Yoshida et al. (U.S. Patent No. 4,690,949; 1987) and Pfister et al. (U.S. Patent No. 5,889,007; 1999), each already of record, for the reasons of record set forth at p.6-9 of the previous Office Action dated May 21, 2010, of which said reasons are herein incorporated by reference.

Response to Applicant's Arguments

Applicant traverses the instant rejection, stating that Tew et al. provides nothing more than a sweeping generalization that, because the compounds therein are inhibitors of Lp-PLA_2, these compounds may have a general application in any disorder that involves endothelial dysfunction and urges that the fact that Tew et al. fails to provide any evidence, e.g., animal testing data, fails to provide any support to these "sweeping generalizations" of the reference and, thus, renders the reference unusable in an obviousness rejection. Applicant opines the Examiner has engaged in hindsight reconstruction by failing to provide any "credible rationale" as to why a person with ordinary skill in the art would have combined these disparate disclosures. Applicant alleges that, though there might be a subset of Alzheimer's patients that also suffers from dementia and *vice versa*, the patient overlap is not sufficient to equate Alzheimer's disease with dementia or to equate a treatment for dementia with a treatment with Alzheimer's disease. Applicant further alleges that Alzheimer's disease is not known to be an Lp-PLA_2 mediated disease, but rather is caused by beta-amyloid dysregulation, and cites to several publications to support his position. Applicant discounts the citations to Cole et al. and Pfister et al., stating that the references are "irrelevant" to the instant claims because (1) the alkyl esters of Cole are not encompassed by the term "active ester forms" as used in the instant claims and (2) Pfister et al. fails to remedy the deficiencies of Tew et al. and Yoshida et al.

Applicant's traversal has been fully and carefully considered, but fails to be persuasive.

Firstly, Applicant states that Tew et al. provides nothing more than a sweeping generalization that, because the compounds therein are inhibitors of Lp-PLA_2, these compounds may have a general application in any disorder that involves endothelial dysfunction and urges that the fact that Tew et al. fails to provide any evidence, e.g., animal testing data, fails to provide any support to these "sweeping generalizations" of the reference and, thus, renders the reference unusable in an obviousness rejection. This is unpersuasive. Such allegations are tantamount to an assertion that the reference is non-enabling for the use of the clavulanic acid derivative compound disclosed therein for the treatment of disease states associated with lipid peroxidation in conjunction with Lp-PLA_2 enzyme activity, such as, *inter alia*, Alzheimer's disease. This argument fails to be persuasive of error because the reference clearly provides a correlation between using the disclosed clavulanic acid derivative compounds for the purpose of treating Alzheimer's disease and provides adequate enabling direction to the skilled artisan to practice the methods disclosed therein, even if the reference fails to prove efficacy using a working example of the same (which, for the record, the Examiner does not concede that a lack of a working example or data is indicative of a lack of efficacy for this particular combination). Regardless, however, references applied under 35 U.S.C. 103(a) constitute prior art for all they teach. See MPEP §2121.01[R-3](II), which states, "Therefore, 'a non-enabling reference may qualify as prior art for the purpose of determining obviousness under 35 U.S.C. 103.' *Symbol Techs. Inc. v. Opticon Inc.*, 935 F.2d 1569, 1578, 19 USPQ2d 1241, 1247 (Fed. Cir. 1991)."

Even if, *arguendo*, Applicant's arguments regarding non-enablement of the prior art were germane to the instant rejection (which the Examiner does not concede), Applicant supports his allegation of non-enablement with assertions that Tew et al. does not enable the treatment of Alzheimer's disease with the clavulanic acid derivative compound disclosed therein because there is no data demonstrating any efficacy or success in the treatment of the same. These arguments are unpersuasive because they are allegations unsupported by facts, which are specifically required to establish non-enablement of a

reference. See MPEP §2121[R-6](I), which states, "When the reference relied on expressly anticipates or makes obvious all of the elements of the claimed invention, the reference is presumed to be operable. Once such a reference is found, *the burden is on applicant to provide facts rebutting the presumption of operability. In re Sasse*, 629 F.2d 675, 207 USPQ 107 (CCPA 1980)." Applicant has provided nothing more than allegations in the absence of facts to support his assertion that Tew et al. is not enabled and, thus, fails to establish a lack of operability of the cited reference.

For the record, Applicant's urging of non-enablement of the reference on the basis that Tew et al. fails to provide data demonstrating efficacy or success in treating Alzheimer's disease with the clavulanic acid derivative compounds therein contradicts the guidance provided in MPEP §2121[R-6](III), which states, "A prior art reference provides an enabling disclosure and thus anticipates a claimed invention if the reference describes the claimed invention in sufficient detail to enable a person of ordinary skill in the art to carry out the claimed invention; "proof of efficacy is not required for a prior art reference to be enabling for purposes of anticipation." *Impax Labs. Inc. v. Aventis Pharm . Inc.*, 468 F.3d 1366, 1383, 81 USPQ2d 1001, 1013 (Fed. Cir. 2006)." Furthermore, MPEP §2121.01[R-3] states that, "A reference contains an 'enabling disclosure' if the public was in possession of the claimed invention before the date of invention. 'Such possession is effected if one of ordinary skill in the art could have combined the publication's description of the invention with his [or her] own knowledge to make the claimed invention." *In re Donohue*, 766 F.2d 531, 226 USPQ 619 (Fed. Cir. 1985)." Thus, contrary to Applicant's assertions, the presumption of operability is not negated on the grounds that proof of efficacy, such as, e.g., in the form of data, has not been provided in the reference.

In addition, Tew et al. clearly provides adequate guidance to actually practice the invention without the need for undue experimentation by one of ordinary skill in the art. Specifically, the reference clearly teaches how to make and use the disclosed clavulanic acid derivatives for the disclosed conditions treatable using such compounds and, therefore, provides adequate enabling direction to one of ordinary

skill in the art to practice the full scope of the invention, even if the reference fails to prove efficacy using a working example (which, again, the Examiner does not necessarily concede that the lack of a working example is indicative of a lack of efficacy for this particular combination). Furthermore, each of the compounds therein is disclosed alternatively as being functional as inhibitors of lipoprotein associated phospholipase A_2 (Lp-PLA_2) for the treatment of diseases associated with lipid peroxidation in conjunction with Lp-PLA_2 activity (of which Alzheimer's disease is particularly named as such a disease) and, therefore, any one or more of the compounds would have been clearly useful for this disclosed therapeutic indication therein. The motivation to select any one of the compounds out of the genus disclosed in Tew et al. is clearly derived from the disclosure of each compound as an alternative embodiment, each of which may be individually selected and each of which is disclosed as equally operative to function as an inhibitor of lipoprotein associated phospholipase A_2 effective for the treatment of the conditions disclosed therein Tew et al. (i.e., of which Alzheimer's disease is specifically named). These facts clearly foreclose the argument that Tew et al. fails to provide enabling guidance for the methods disclosed in the reference because the disclosure provides clear guidance as to how to make, use and practice the disclosed method of treatment. Once again, note that, per the MPEP, a reference does not have to *prove efficacy* to constitute an enabled disclosure. Rather, so long as the reference provides a clear description of the invention, which, when coupled with the skilled artisan's own knowledge, is sufficient to describe how to make and use the invention as described, the reference provides an enabled disclosure. In this case, the fact that Tew et al. may not provide a definitive exemplification of the compound(s) for treating Alzheimer's disease is an insufficient basis to conclude non-enablement of the reference when Tew et al. clearly provides adequate disclosure and guidance to place the claimed invention in possession of the public *without the need to resort to undue experimentation.*

Secondly, Applicant opines the Examiner has engaged in hindsight reconstruction by failing to provide any "credible rationale" as to why a person with ordinary skill in the art would have combined

these disparate disclosures. This is unpersuasive. Applicant is reminded that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. However, so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the Applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). Considering the fact that the present rejection under 35 U.S.C. 103(a) relies solely on the knowledge and motivation that was generally available to one of ordinary skill in the art at the time of the invention (as clearly elucidated *supra*, as well as in each of the previous Office Actions) and does not improperly rely upon Applicant's disclosure, the assertion that the present rejection is made with impermissible hindsight reconstruction is unpersuasive. Moreover, the allegation that the rejection provides no "credible rationale" is not a point well taken because the rejection relies solely upon the knowledge present in the art at the time of the invention and provides clearly elucidated reasons for combining the cited disclosures.

Thirdly, Applicant alleges that, though there might be a subset of Alzheimer's patients that also suffers from dementia and vice versa, the patient overlap is not sufficient to equate Alzheimer's disease with dementia or to equate a treatment for dementia with a treatment with Alzheimer's disease. This is unpersuasive because Applicant has mischaracterized the grounds for rejection. Yoshida et al. was cited for its teaching that, within the general population of Alzheimer's disease patients taught by Tew et al., there are clearly patients within this population that also suffer concomitantly from dementia. In other words, of the total general population of Alzheimer's disease patients, there is clearly a subpopulation that suffers from both Alzheimer's disease and dementia. Thus, the practice of administering the clavulanic acid derivative compounds of Tew et al. for the purpose of treating Alzheimer's disease patients *per se* would also, therefore, circumscribe its practice in a subpopulation of Alzheimer's disease patients, such as those patients suffering from both Alzheimer's disease and dementia (as evidenced by Yoshida et al.), which meets the instantly claimed method. As a result, while it may very well be true that the two

populations are not strictly identical (i.e., such that every dementia patient is an Alzheimer's patient and vice versa), the fact remains that the two patient populations overlap in such a way that there is a population (within the larger population of Alzheimer's patients *per se*) that are both Alzheimer's and dementia patients and are, thus, subject to the practice of the method(s) of the cited prior art. On these grounds, the treatment of patients with Alzheimer's disease and dementia is clearly suggested by the combination of cited prior art references, absent factual evidence to the contrary.

Fourthly, Applicant further alleges that Alzheimer's disease is not known to be an Lp-PLA_2 mediated disease, but rather is caused by beta-amyloid dysregulation, and cites to several publications to support his position. This is unpersuasive. Applicant's reference to these various publications to support his allegation that Alzheimer's disease is apparently not known to be an Lp-PLA_2 mediated disease has been fully considered, but fails to negate the teaching of Tew et al. Though Applicant attempts to support his position by alleging that each of the publications to i.e., Schaloske et al., Bhatti et al., Karakas et al., or Sanchez-Mejia et al. fails to mention Alzheimer's disease, such an allegation is tantamount to an assertion that the absence of evidence provided in these references regarding the link between Lp-PLA_2 and Alzheimer's disease is evidence that a link between the two does not exists in the art. This is pure speculation of Counsel and fails to be persuasive. Absence of evidence is not evidence of absence. The fact that these references do not discuss Alzheimer's disease and Lp-PLA_2 does not support the allegation that there is no correlation between the two. For example, the Bhatti et al. reference discusses the relationship between Lp-PLA_2 and cardiovascular disease. The fact that Alzheimer's disease is not discussed therein is not surprising since that is not the purpose of the article. Oddly, though, Applicant erroneously interprets this fact as evidence that there is no relationship between Lp-PLA_2 and Alzheimer's disease. Such an allegation has no factual basis in the cited literature and, therefore, is unpersuasive.

The only article tangentially related to the instantly claimed subject matter is the Farooqui et al. reference, which discusses phospholipase A_2 activity in the context of neurologic disorders. However,

Farooqui et al. only discusses PLA_2 isoforms other than Lp-PLA_2, whereas Lp-PLA_2 is the focus of Tew et al. Thus, Farooqui et al. fails to provide any basis to conclude that there is no relationship between the specific Lp-PLA_2 isoform and the pathogenesis of Alzheimer's disease. Accordingly, Applicant's repeated arguments that Alzheimer's disease is not a disease mediated by Lp-PLA_2 are clearly unpersuasive, even in light of the publications cited in the Remarks, which are deficient for the reasons *infra*.

Fifthly, and lastly, Applicant discounts the citations to Cole et al. and Pfister et al., stating that the references are "irrelevant" to the instant claims because (1) the alkyl esters of Cole are not encompassed by the term "active ester forms" as used in the instant claims and (2) Pfister et al. fails to remedy the deficiencies of Tew et al. and Yoshida et al. This is unpersuasive. With regard to Applicant's comments concerning the alkyl esters of Cole et al. not being encompassed by the term "active ester forms" as used in the instant claims, this is unpersuasive because the instantly claimed term "active ester form" is not particularly limited to specific ester forms such that it would have been clear from Applicant's definition that the alkyl esters of Cole et al. are excluded from the instant claims as alleged by Applicant. Applicant is attempting to impute a limiting definition to the term "active ester form" as used in the instant claims that does not exist in the instant specification in order to distinguish the instant claims from the cited prior art, which is properly found unpersuasive.

Furthermore, with regard to Applicant's comments concerning the application of Pfister et al., Applicant's consideration of Pfister et al. individually and not in combination with the other cited prior art references is tantamount to examining the reference inside of a vacuum. Such an argument fails to be persuasive in establishing non-obviousness because it is the *combined* teachings that are the basis for a proper conclusion of obviousness, not each individual reference alone. In other words, it must be remembered that the references are relied upon in combination and are not meant to be considered separately. To properly conclude obviousness of an invention does not require the claimed invention to

be expressly suggested in its entirety by any one single reference under 35 U.S.C. 103(a). Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. Please reference *In re Young*, 403 F.2d 754, 159 USPQ 725 (CCPA 1968) and *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981).

For these reasons *supra*, and those previously made of record at p.6-9 of the Office Action dated May 21, 2010, rejection of claims 2-6 and 11 is proper.

Conclusion

Rejection of claims 2-6 and 11 is proper.

Claims 1, 7-10 and 12-17 remain withdrawn from consideration pursuant to 37 C.F.R. 1.142(b).

No claims of the present application are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie A. Royds whose telephone number is (571)-272-6096. The examiner can normally be reached on Monday-Friday (9:00 AM-5:30 PM).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on (571)-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Leslie A. Royds/
Primary Examiner, Art Unit 1614

October 15, 2010